IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

AMANDA NOEL and JOSEPH NOEL,

Plaintiffs,

vs.

BAYER CORPORATION, et al.,

Defendants.

CV 20-27-BLG-SPW

ORDER GRANTING MOTION TO DISMISS

Before the Court is Defendants' (collectively "Bayer") motion to dismiss the Complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). (Doc. 7.)[1] Plaintiff Amanda Noel filed a response, (Doc. 20), and Bayer filed a reply, (Doc. 21). For the following reasons, the Court grants the motion but will provide Noel leave to amend her complaint.

I. Background

Bayer manufactures and sells a female contraceptive device known as Essure. (Doc. 1 at ¶ 16.) Essure is a permanent form of birth control that is intended to cause

[1] Noel served Bayer Essure Inc. after the other defendants filed the motion to dismiss. Bayer Essure Inc. then filed its own motion to dismiss and adopted the first motion's reasoning. (Doc. 22.) The Noels did not object to Bayer Essure Inc. essentially joining the other defendants' initial motion to dismiss. (Doc. 25.) This Order addresses both motions and includes Bayer Essure Inc. in the collective name, "Bayer."

bilateral blockage of the fallopian tubes. (*Id.* at ¶ 41.) Bayer designed, marketed, and manufactured Essure to be implanted without anesthesia through a non-surgical outpatient procedure. (*Id.* at ¶ 51.)

Noel was implanted with the Essure device in November 2012. (*Id.* at ¶ 109.) After the procedure, she began to suffer from severe pelvic pain, excessive and frequent menses, and severe and excessive bleeding during menstruation. (*Id.* at ¶ 110.) Because of these complications, in April 2017, she underwent a surgery to remove the Essure device along with her fallopian tubes. (*Id.* at ¶ 111.)

Noel filed the instant Complaint against Bayer alleging eleven counts: (1) Negligent Training; (2) Negligent Entrustment; (3) Negligent Distribution and Overpromotion; (4) Negligence – Risk Management; (5) Breach of Express Warranty; (6) Unfair Trade Practices and Consumer Protection; (7) Fraudulent Concealment; (8) Fraudulent Misrepresentation; (9) Negligent Misrepresentation; (10) Strict Liability; and (11) Negligent Design. (*Id.* at ¶¶ 137–273.) Bayer now seeks dismissal of her claims, arguing federal law preempts them and they are otherwise deficient. (Doc. 7-1 at 8.)

II. Discussion

When Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), it "imposed a regime of detailed federal oversight" for medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316

(2008). The MDA separates medical devices into three categories with progressively more stringent regulations. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). A Class III device, such as Essure, "presents a potential unreasonable risk of illness or injury" and therefore incurs the most stringent regulations. Section 360c(a)(1)(C)(ii)(II). Class III devices must complete a thorough review and premarket approval process through the FDA before a company may market them. *Buckman*, 531 U.S. at 344. The process requires demonstrating "reasonable assurance of [the device's] safety and effectiveness." Section 360c(a)(1)(C). Premarket approval is "rigorous," and requires a manufacturer to submit what is typically "a multivolume application" with numerous components. *Riegel*, 552 U.S. at 317.

After the FDA grants a device premarket approval, the MDA forbids a manufacturer from making, without FDA permission, "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)). An applicant wishing to make such a change must apply for supplemental premarket approval through the FDA, which the FDA evaluates under largely the same criteria as the initial application. *Id.* (citing § 360e(d)(6); 21 CFR § 814.39(c)).

Section 360i also subjects premarket-approved devices to several reporting requirements. An applicant must inform the FDA of any new clinical investigations

or scientific studies concerning the device of which the applicant knows or reasonably should know. *Riegel*, 552 U.S. at 319 (citing 21 CFR § 814.84(b)(2)). The applicant must also "report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Id.* (citing § 803.50(a)). The FDA must withdraw a device's approval if it determines the device is unsafe or ineffective under the conditions in its labeling. *Id.* (citing 21 USC § 360e(e)(1)).

Critically, upon its passage, the MDA pre-empted and otherwise limited independent state obligations for medical devices. It includes an express federal pre-emption provision stating, as a general rule:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Section 360k(a) therefore expressly pre-empts state requirements, including common law requirements, to the extent that they are "different from, or in addition to" the requirements imposed by federal law. *Riegel*, 552 U.S. at 330. Not all state requirements are pre-empted, however. States can still provide remedies for claims premised on a violation of the FDA regulations as long as "the state duties in such a

case 'parallel,' rather than add to, federal requirements." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). Furthermore, under federal law, the MDA does not provide a private right of action for enforcement. Section 337 ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *see also Buckman*, 531 U.S. at 348 (holding the FDCA impliedly pre-empted the plaintiffs' fraud-on-the-FDA claims because the FDCA empowers the FDA to punish and deter fraud against it, and allowing state-law claims would skew the balance of statutory objectives).

Therefore, the actions a plaintiff may bring regarding a medical device are few. The plaintiff can neither maintain such an action under federal law alone nor under any state law that is "different from, or in addition to" the FDCA. Sections 337, 360k(a). Instead, the plaintiff must bring her action under a parallel state law. Put another way, "The plaintiff must be suing for conduct that *violates* the FDCA (or else [her] claim is expressly pre-empted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly pre-empted under *Buckman*)." *In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (emphasis in original); *accord Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). Under this framework, the Court turns to Noel's claims against Bayer.

a. Design and Manufacturing Defects (Counts X and XI)

Noel primarily alleges Bayer failed to design Essure in a safe and reasonable manner. (Doc. 1 at ¶¶ 242–73.) She also asserts Bayer departed from the design the FDA approved for the device. She alleges Bayer used "nonconforming material," (Doc. 1 at ¶¶ 40, 77, 78(e), 132, 251(c), 261(e)), nonsterile cages, (*Id.* at ¶¶ 40, 77), and that the device was "adulterated," (*Id.* at ¶¶ 27–29, 34, 39, 63, 88, 106, 132, 168). She alleges the changes were not approved by the FDA because the FDA cited Bayer for them. (*Id.* at ¶¶ 31, 217.) She also alleges Bayer manufactured Essure without a license and at an unlicensed facility. (*Id.* at ¶¶ 31(d),(e), 40, 77(c),(d), 106.)

In *De La Paz v. Bayer HealthCare Ltd. Liab. Co.*, 159 F. Supp. 3d 1085, 1094–95 (N.D. Cal. 2016), the California Northern District Court addressed nearly identical claims and issues stemming from a plaintiff's complaint against Bayer for the Essure device. Like Noel, De La Paz claimed the Essure device had fundamental design defects. *Id.* at 1090. De La Paz also claimed her specific device was adulterated because Bayer used nonconforming material, non-sterile cages, and manufactured Essure without a license and at an unlicensed facility. *Id.* at 1094–95.

The district court first noted it was nearly impossible for a design-defect claim to survive pre-emption because such a claim would challenge the FDA-approved design. *Id.* at 1092 ("*Every* design-defect claim considered within our circuit has

been held pre-empted (such a claim would require allegations of deviations from the FDA-approved design).") (emphasis in original).

The district court then turned to De La Paz's specific manufacturing-defect claims. It explained that a device is adulterated under the MDA if "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements" in the FDA's requirements for that device. *Id.* (quoting § 351(h)). To escape pre-emption, the complaint must allege the irregularities resulted in a manufacturing defect that caused the plaintiff's injuries. The claim could not exist solely because it violated the MDA's requirements. *Id.* (citing *Buckman*, 531 U.S. at 353). Finding De La Paz had not alleged the defects caused her injuries, the court dismissed the claims, but it provided that De La Paz could seek leave to amend. *Id.*

This Court finds the California Northern District Court's reasoning was sound. First, Noel's design-defect claims are pre-empted on their face. The parties do not dispute that the FDA approved the Essure device. (Doc. 1 at ¶ 22.) Noel alleges her injuries were caused by Bayer's "negligent and reckless conduct" in researching, designing, and testing Essure, along with other similar design-defect claims. (Doc. 1 at ¶¶ 267.) A claim that Essure's design is deficient seeks to invalidate the FDA's approval of the device and is inherently pre-empted (as opposed to a manufacturing-defect claim, which may be specific to a plaintiff's

device). *See Riegel*, 552 U.S. at 330 (holding a device manufacturer could not be liable under state tort law "notwithstanding compliance with the relevant federal requirements").

The Court turns, then, to Noel's claims that her device was adulterated—i.e., manufacturing-defect claims. Unlike her design-defect claims, these claims may survive pre-emption where they allege Bayer's manufacturing of Noel's device did not conform to the FDA's requirements (something Montana law would provide a remedy for, *see* Mont. Code Ann. § 27–1–719; *Sternhagen v. Dow Co.*, 935 P.2d 1139 (Mont. 1997)). However, like De La Paz, Noel's complaint fails to allege facts establishing that Essure's manufacturing defects caused her injuries. Her complaint contains only the conclusory allegation that "the Essure device did not perform as warranted and instead caused the injuries described above." (Doc. 1 at ¶ 262.) Her manufacturing defects claims therefore do not contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Nayab v. Capital One Bank (USA), N.A.*, 942 F.3d 480, 495–96 (9th Cir. 2019) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Accordingly, both Noel's design-defect and manufacturing-defect claims will be dismissed.

b. Failure to Warn (Counts VII and X)

Noel alleges Bayer had a duty to disclose numerous consumer complaints about the Essure device and to warn others of the device's defects. (Doc. 1 at ¶¶ 22,

23, 70, 136, 212, 218, 251(d), 258, 261(b)). Noel alleges Bayer had duties to disclose the information and warn the FDA, healthcare providers, and Noel herself. (*Id.*)

"Where a federal requirement *permits* a course of conduct and the state makes it *obligatory*, the state's requirement is in addition to the federal requirement and thus is pre-empted." *In re: Medtronic*, 623 F.3d at 1205 (emphasis added). Therefore, "Even if federal law *allowed* [a device manufacturer] to provide additional warnings, as Plaintiffs alleged, any state law *imposing* an additional requirement is pre-empted by § 360k." *Id.* (emphasis in original).

First, Noel points to no FDA requirement for Bayer to report consumer complaints directly to healthcare providers and consumers or to update its warnings and labeling as Bayer learns of issues with the device. Therefore, any claims grounded in Montana law making such reports and warnings obligatory are pre-empted. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("Because [21 C.F.R.] § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation."); *see also* 21 C.F.R. § 808.1(d)(6)(ii) ("Where . . . [a state-law] prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling

requirement, then the prohibition will be pre-empted if the requirement is different from, or in addition to, a Federal requirement established under the act.").

Second, under federal law, device manufacturers must report any incident to the FDA where their device "may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). However, Montana law provides no such parallel duty.

Noel argues Montana law does create a parallel duty because a manufacturer can be found liable if it failed to adequately warn of dangers which would not be readily recognized by an ordinary user of the product. She cites two cases in support.

In *Patch v. Hillerich & Bradsby Co.*, 257 P.3d 383, 386–87 (Mont. 2011), plaintiffs brought a lawsuit against a baseball bat manufacturer for a failure to warn that the manufacturer's aluminum bat would greatly increase the velocity of a batted ball. The Montana Supreme Court held the manufacturer's duty to warn extended all the players because they were foreseeable users or consumers. *Id.* at 388.

In *Stevens v. Novartis Pharm. Corp.*, 247 P.3d 244, 257–60 (Mont. 2010), the Montana Supreme Court analyzed whether the duty to warn extended to any healthcare professionals responsible for a patient's care. The Court ultimately did not resolve the issue, but it speculated the duty to warn would likely include treating physicians and other healthcare professionals, even if those professionals were not the prescribing or primary physician. *Id.* at 259–60.

While Montana law provides for a common law claim for a failure to warn, both cases Noel cites are distinguishable. A government regulator is not a foreseeable user or consumer of a product. *See Patch*, 257 P.3d at 388. Nor is it a healthcare professional responsible for a patient's care. *See Stevens*, 259–60; *see also Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018) ("The FDA is not a health care provider and does not prescribe anything for patients."). In neither case did the Montana Supreme Court hold that a manufacturer must warn *the FDA* (or government regulators generally) of known dangers. Noel's failure-to-warn-the-FDA claims are impliedly pre-empted and will be dismissed.

c. Misrepresentation-Based Claims (Counts V–IX)

In her complaint, Noel alleges Bayer falsely advertised, warranted, and represented that Essure "was safer and more effective than other methods of birth control," (Doc. 1 at ¶ 24), was a "quick and easy" and "non-surgical" outpatient procedure, (*Id.*), was "the best alternative for permanent female sterilization," (*Id.* at ¶ 115), and that "Physicians must be signed-off to perform Essure procedures," (*Id.* at ¶ 93). Bayer argues the claims for breach of warranty and misrepresentation are pre-empted.

When a claim challenges marketing that complied with FDA-approved requirements, courts have held it is pre-empted because "success on those claims requires a showing that the FDA requirements themselves were deficient." *Gomez*

v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 933 (5th Cir. 2006); *accord Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997); *De La Paz*, 159 F. Supp. 3d at 1098; *Suckow v. Medtronic, Inc.*, 971 F. Supp. 2d 1042, 1049 (D. Nev. 2013). Such claims "cannot be presented to a jury because, if successful, they would be inconsistent with the federal regulatory requirements." *Gomez*, 442 F.3d at 933. This is the case here: though Noel argues her warranty claims are not pre-empted because they do not allege the labelling was defective, (Doc. 20 at 29), challenging them would require her to show the FDA requirements were themselves deficient. *See Gomez*, 442 F.3d at 933.

Instead, to survive pre-emption, the express warranties must have gone "beyond" the statements the FDA approved. *De La Paz*, 159 F. Supp. 3d at 1098 (citing *Suckow*, 971 F. Supp. 2d at 1049). When the express warranties are functionally equivalent to the approved language, courts have held they are pre-empted.[2] *See, e.g.*, *McLaughlin v. Bayer Corp.*, 2017 WL 697047, at *12–15

[2] 21 C.F.R. § 801.1(d)(1) states 21 U.S.C. § 360k does not preempt State or local requirements "of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." Noel argues this regulation clearly indicates warranty claims are not preempted because they are state laws of general applicability. She is mistaken. The regulation relates only to state requirements "of general applicability" whose purpose relates to "*other products in addition to devices*" or to unfair trade practices "in which the requirements *are not limited to devices*." 21 C.F.R. § 801.1(d)(1) (emphasis added). Her claims relate to alleged express warranties made about the Essure device itself, not other products in addition to the device. Nevertheless, the Supreme Court has found this regulation is ambiguous and "can add nothing to [the] analysis but confusion" in the face of the plain text of 21 U.S.C. § 360k. *Reigel*, 552 U.S. at

(E.D. Pa. Feb. 21, 2017) (hereinafter "*McLaughlin II*") (dismissing claims regarding statements that were "completely consistent with statements in FDA-approved materials and do not undermine—or overstate—the approved and/or required statements"); *De La Paz*, 159 F. Supp. 3d at 1098 (dismissing where "the statements conformed to statements approved by the FDA"); *Norman v. Bayer Corp.*, 2016 WL 4007547, at *5–6 (D. Conn. July 26, 2016) (dismissing where challenged language was "so similar to the approved language as to be substantively the same"); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 603–05 (Mo. Ct. App. 2017) (affirming dismissal of misrepresentation and warranty claims where the challenged statements were "functionally equivalent to those in the Essure labeling").

The Court agrees with Bayer that the alleged misrepresentations here are functionally equivalent to FDA-approved language. Bayer's first alleged misrepresentation is that Essure "was safer and more effective than other methods of birth control." (Doc. 1 at ¶ 24). This is functionally equivalent to FDA-approved statements that Essure is "99.83% effective," along with an approved comparison showing Essure as having a lower failure rate than a vasectomy, tubal ligation, and several temporary birth control methods. (Doc. 21-2 at 4, 7–11.)[3] The second alleged misrepresentation is that Essure is a "quick and easy" and "non-surgical"

329. Thus, like the Supreme Court determined in *Reigel*, this Court concludes "the regulation fails to alter [its] interpretation of [§ 360k] insofar as the outcome of this case is concerned." *Id.* at 330.

[3] Doc. 21-2 is an FDA-approved Essure patient guide printed in December 2013. The Court takes judicial notice of this and Bayer's other exhibits under Federal Rule of Evidence 201(b).

outpatient procedure. (Doc. 1 at ¶ 51.) This is functionally equivalent to FDA-approved statements that "Essure is a simple procedure that can be done in 10 minutes in your doctor's office," and that Essure is "Non-Surgical" and "No General Anesthesia Required." (Doc. 21-2 at 4.) The third allege misrepresentation is that "Physicians must be signed-off to perform Essure procedures." (Doc. 1 at ¶ 93). This is also functionally equivalent to FDA-approved statements that Essure "should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the Essure training program." (Doc. 7-7 at 2.) None of the alleged misrepresentations here go beyond the FDA's approved language. Accordingly, each of Noel's claims about these alleged misrepresentations are pre-empted and will be dismissed.

Finally, Noel also alleges Bayer misrepresented that Essure was "the best alternative for permanent female sterilization." (Doc. 1 at ¶ 115). This is clearly an opinion and cannot be the basis for a misrepresentation claim. *See* Restatement (Second) of Torts § 538A (1977) ("A representation is one of opinion if it expresses only . . . [the speaker's] judgment as to quality, value, authenticity, or other matters of judgment."). Likewise, Noel's claim about this representation will be dismissed.

d. Negligent Training for Essure (Count I)

Noel alleges Bayer "undertook an independent duty to train physicians on how to properly use Essure and place the micro-inserts, which failed to abide by FDA training guidelines." (Doc. 1 at ¶ 138.) She alleges Bayer "had a duty to adequately train the implanting physicians on how to place Essure using its own delivery system, certify the implanting physicians, and oversee this particular procedure," and it also "had a duty to train the physician in hysteroscopy in a reasonably safe manner." (*Id.* at ¶ 139.) She argues Bayer breached this duty and parallel state laws, "thereby departing from the FDA-approved guidelines" by failing to train her physicians in several aspects. (*Id.* at ¶ 141.) Bayer argues the claims are pre-empted, that Montana law provides no parallel requirement to train, and that, regardless, Noel has offered no factual support that the allegedly negligent training differed from the FDA-approved training and caused her injuries. (Doc. 7-1 at 19–22.)

In *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804 (E.D. Pa. 2016) (hereinafter "*McLaughlin I*"), the Eastern District of Pennsylvania faced nearly identical claims against Bayer and dispensed with the parties' arguments with sound reasoning. First, the district court concluded that, "at least to the extent that the claim alleges that Bayer failed to abide by FDA-approved training [requirements], the negligent training claim does not seek to impose training requirements different from those in the federal requirements." *Id.* at 816. Therefore, the plaintiff was asserting

a permissible, parallel state-law claim. *Id.* The same is true here: to the extent Noel alleges Bayer did not abide by the FDA-approved training requirements, she may be asserting a parallel claim under Montana law.[4] *See* (Doc. 1 at ¶ 138.) Therefore, the Court turns to whether Montana law provides for such claims.

Bayer argues it does not. Bayer states Montana recognizes failure-to-train claims only in the context of a direct employer-employee relationship. (Doc. 7-1 at 21–22.) However, neither of the cases it cites have such a holding. Rather, they discuss employer liability under the theory of *respondeat superior*—something not at issue here. *See Maguire v. State*, 835 P.2d 755, 758–60 (Mont. 1992) (discussing employer liability for an employee's intentional torts); *Peschel v. City of Missoula*, 664 F. Supp. 2d 1149, 1168 (D. Mont. 2009) (discussing issues related to negligent hiring and retention of an employee). Clearly Noel does not allege her physicians were employees of Bayer. Instead, she alleges Bayer independently undertook a duty to train her physicians in using the Essure device. (Doc. 1 at ¶¶ 91, 138.)

Turning again to *McLaughlin I*, the district court recognized that under Pennsylvania law, "in certain contexts, one who undertakes to render services to another may be subject to liability to a third party for failure to exercise due care in

[4] There is one exception, however. Noel alleges that Bayer breached a duty to "supervise" her implanting physicians. The Court is unable to discern this requirement from the FDA-approved training requirements. Therefore, it is a requirement "different than, or in addition to," the FDA requirements and is expressly pre-empted. *Riegel*, 552 U.S. at 323–25.

rendering those services, when the services were necessary for the protection of that third party." 172 F. Supp. 3d at 817. In support, the district court cited *Seebold v. Prison Health Sys., Inc.*, 57 A.3d 1232, 1244-45 (Pa. 2012)—a case that relied on the Restatement (Second) of Torts § 324A.[5] *Id.*

Recently, the Montana Supreme Court adopted the same restatement provision in *Md. Cas. Co. v. Asbestos Claims Court*, 460 P.3d 882 (Mont. 2020). It held the provision applies whenever a court must determine "whether an alleged tortfeasor owed a common law duty of reasonable care to a particular claimant or class based on an affirmative undertaking to render aid or services to a third party who was the direct cause of the harm at issue." *Id.* at 901. It also discussed three alternative factual predicates required to give rise to the special duty and resulting liability: (1) where the first party's failure to exercise reasonable care increased the risk of the subject harm; (2) where the first party has undertaken to perform a duty owed by the other to the party harmed; or (3) where the harm is suffered because of reliance of the third party or the party harmed upon the undertaking. *Id.* at 901–04.

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[5] Restatement (Second) of Torts § 324A states:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
>
> (a) his failure to exercise reasonable care increases the risk of such harm, or
>
> (b) he has undertaken to perform a duty owed by the other to the third person, or
>
> (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

With the Montana Supreme Court's adoption of § 324A, this Court concludes Montana law provides a parallel claim for the negligent training Noel alleges. Taking the facts in the complaint as true, Bayer undertook to render services (Essure training) to another (physicians providing the device to their patients). Bayer should recognize the training as necessary for the protection of third parties (patients like Noel), and Bayer is subject to liability to those patients for physical harm resulting from its failure to exercise reasonable care in training the physicians if, for example, its failure to exercise reasonable care increased the risk of such harm to the patients. *See Md. Cas. Co.*, 460 P.3d at 901–04; Restatement (Second) of Torts § 324A.

One issue remains, however: Noel's complaint fails to allege sufficient facts demonstrating her injuries were a proximate cause of Bayer's negligent training. Though it states Noel was harmed when Bayer failed to adequately train her physician, it offers no facts indicating how that training differed from the FDA-approved requirements and how that led to her injuries. The Complaint must show "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Accordingly, Noel's claims relating to negligent training fail to state a claim upon which relief can be granted and will be dismissed.

e. Negligent Entrustment and Training for Hysteroscopic Equipment (Counts I and II)

Noel alleges Bayer negligently provided and entrusted sophisticated hysteroscopic equipment to implanting physicians in order to sell its product. (Doc.

1 at ¶ 148.) She alleges Bayer knew the implanting physicians were not competent to use the equipment but provided it anyway. (*Id.* at ¶ 149.) Bayer argues these claims relate directly to the safety of Essure, seek to impose different or additional requirements, and are therefore pre-empted. (Doc. 7-1 at 28.) Noel responds that Bayer's hysteroscope contracts with implanting physicians are completely divorced from the FDA regulation of Essure, as was any agreement to train the physicians in the use of the equipment. (Doc. 20 at 30–31.)

Noel's complaint states that Essure consists of three components all intended for single use: (1) two micro-inserts; (2) a disposable delivery system, and (3) a disposable split introducer. (Doc. 1 at ¶ 42.) The device is placed in a woman's fallopian tubes via the disposable delivery system "and under hysteroscopic guidance (camera)." (*Id.* at ¶ 43.) The complaint states, "The hysteroscopic equipment needed to place Essure was manufactured by a third party, is not a part of Defendants' [conditional premarket approval], and is not a part of Essure." (*Id.* at ¶ 44.) However, because Noel's implanting physician did not have hysteroscopic equipment, Bayer provided it as part of a marketing strategy. (*Id.* at ¶¶ 44, 151.)

Noel alleges Bayer trained physicians on how to use the hysteroscopic equipment but did so negligently. (*Id.* at ¶¶ 56, 127.) She alleges that because Bayer provided the equipment, it had a duty to adequately train the physicians to use it in a reasonably safe manner, or "at the very least, ensure that the implanting physician

was competent in hysteroscopy before providing them with the hysteroscopic equipment needed to place Essure." (*Id.* at ¶ 140.)

Noel's hysteroscopic equipment claims are not expressly pre-empted because neither Essure's conditional premarket approval nor the FDA requirements it entails encompass the hysteroscopic equipment. Taking Noel's factual allegations as true, the Court finds that the hysteroscopic equipment and Essure are two separate products, manufactured by different parties. Though the equipment is required to implant Essure, there is no allegation it is the equipment's only use, and the FDA did not require Bayer to provide the equipment or train physicians in the equipment's use as part of Essure's conditional premarket approval. That is something Bayer undertook independently to increase its market share.

Furthermore, were a jury to find that Bayer negligently entrusted unqualified physicians with the hysteroscopic equipment or negligently trained them in its use, the finding would not necessarily weigh on whether the Essure device itself was safe. A jury could find Noel's physician failed to properly insert and implant Essure because of the physician's misuse of the hysteroscopic equipment. That improper implantation could have allowed the device to dislodge or malfunction in some other way to cause Noel's injuries, even if the device was otherwise safe. That misuse could be linked to Bayer's negligent entrustment and training.

In this scenario, the jury would not need to consider whether the Essure device itself was safe. Thus, unlike some of Noel's other claims, the claims relating to the hysteroscopic equipment are not claims where "success . . . requires a showing that the FDA requirements themselves [are] deficient." *Gomez*, 442 F.3d at 933. They are not pre-empted.

Moreover, as the Court concluded before, Montana law provides for an action for negligent training under these facts. *See Md. Cas. Co.*, 460 P.3d at 901–04. Montana law also provides for a claim of negligent entrustment: "a person who supplies a chattel to another whom the supplier knows or has reason to know is likely to use it in a manner involving unreasonable risk of physical harm is subject to liability for the resulting physical harm." *McGinnis v. Hand*, 972 P.2d 1126, 1129 (Mont. 1999).

Even still, the complaint fails to allege a factual, causal link between the alleged negligent entrustment and training and Noel's injuries. It states only that "[t]his breach caused [Noel's] damages described herein." (Doc. 1 at ¶ 157); *accord* (*Id.* at ¶ 142). These claims must be based on "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft*, 556 U.S. at 678. Accordingly, the counts fail to state a claim upon which relief can be granted and will be dismissed.

f. Negligent Distribution and Overpromotion (Count III), Negligent Risk Management (Count IV), and Unfair Trade Practices and Consumer Protection (Count VI)

Noel's remaining three counts are either pre-empted or not cognizable claims under Montana law. First, Noel alleges Bayer had a duty to distribute and promote Essure in a reasonably safe manner—a duty it breached by requiring physicians to purchase two Essure kits per month, regardless of whether the physician used them or not. (Doc. 1 at ¶¶ 163–65.) Despite this, there is no reason to suspect that requiring physicians to purchase two devices per month would pose any danger unless the Essure device itself was defective, which would require showing the FDA requirements themselves were deficient. *See Gomez*, 442 F.3d at 933. To that extent, Noel's claim is pre-empted and will be dismissed.

Second, Noel alleges Bayer had a duty to prepare and have in place a risk management procedure to deal with consumer complaints and breached that duty by failing to have such a procedure. (Doc. 1 at ¶¶ 175–76.) However, the risk management procedure Noel details is essentially one to report issues with Essure to the FDA. (*Id.* at ¶¶ 177–81.) As the Court described above, Montana law does not recognize a claim for failing to report Essure's issues to the FDA. Therefore, this claim is impliedly pre-empted under *Buckman*, 531 U.S. at 348, and will be dismissed.

Finally, Noel alleges a claim for unfair trade practices. Noel primarily premises this claim on the allegation that her "loss was caused by justifiable reliance of deceptive conduct, specifically the warranties and advertisements outlined in the preceding paragraphs and the active concealment of adverse incidents, use of non-conforming product, and incomplete risk analysis." (Doc. 1 at ¶ 205.) The unfair trade practices count is founded on expressly or impliedly pre-empted claims. Accordingly, this claim is also dismissed.

g. Leave to Amend

Noel seeks leave to amend her complaint to allege sufficient facts to establish causation for her claims that could otherwise survive pre-emption. (Doc. 20 at 2.) "The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Court will grant Noel leave to amend.

The Court is cognizant that product liability claims present a level of difficulty at the pleading stage because "much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). Oftentimes, discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claims. *Id.* In the case of medical devices, other courts have held that, "in analyzing the sufficiency of pleadings, 'a plaintiff's pleading burden should be commensurate with the amount of information available

to them.'" *Id.* at 561 (quoting *In re: Medtronic*, 623 F.3d at 1212 (Melloy, J., dissenting); *accord Bass v. Stryker Corp.*, 669 F.3d 501, 511 (5th Cir. 2012); *Bowlen v. Coloplast A/S*, 2019 WL 4597570, at *3 (W.D. Pa. Sept. 23, 2019); *Burgos v. Satiety, Inc.*, 2011 WL 1327684, at *4 (E.D.N.Y. Apr. 5, 2011).

Even with this standard, Noel's complaint fails to state a claim regarding the issues that could otherwise escape pre-emption. At this point, those issues are too intertwined with pre-empted issues (for example, Noel's design-defect and manufacturing-defect claims). They fail to give Bayer fair notice of the claims against it. *See* Fed. R. Civ. P. 8. Nevertheless, Noel will have the opportunity to amend her complaint.

III. Conclusion

To survive express or implied pre-emption, Noel's claims against Bayer regarding the Essure medical device must be for Bayer's alleged violations of Essure's FDA-approved requirements, but the claims must also be rooted in Montana law. The design-defect, express warranty (including false statements and fraudulent concealment), negligent distribution and overpromotion, and negligent risk management claims—and the claims based on a failure to warn Noel and her healthcare providers—are expressly pre-empted. The claims based on a failure to warn (or report adverse events) to the FDA are impliedly pre-empted because there are no parallel requirements based on Montana law. These pre-empted claims will

be dismissed with prejudice. The remaining claims (manufacturing defect, negligent training, negligent training and entrustment regarding the hysteroscopic equipment, and unfair trade practices) are dismissed without prejudice for failure to state a claim. Accordingly,

IT IS HEREBY ORDERED:

1. Defendant Bayer's Motions to Dismiss (Doc. 7; Doc. 22) are **GRANTED**.
2. The following claims are **DISMISSED WITH PREJUDICE**:
    a. design defect (Count XI and portions of Count X),
    b. negligent distribution and overpromotion (Count III),
    c. negligence – risk management (Count IV),
    d. breach of express warranties (Count V),
    e. fraudulent concealment (Count VII),
    f. fraudulent misrepresentation (Count VIII),
    g. negligent misrepresentation (Count IX), and
    h. unfair trade practices (Counts VI).
3. The following claims are **DISMISSED WITHOUT PREJUDICE**:
    a. negligent training regarding the Essure device (Count I),
    b. negligent training regarding the hysteroscopic equipment (Count I),
    c. negligent entrustment of the hysteroscopic equipment (Count II), and
    d. manufacturing defect (Count X).

4. Plaintiff Amanda Noel is **GRANTED LEAVE TO AMEND** her complaint in accordance with this Order until September 23, 2020.

The clerk of Court shall notify the parties of this Order.

DATED this 26th day of August 2020.

Susan P. Watters

SUSAN P. WATTERS
United States District Judge